UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MLH9331

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2013 SEP 20 PM 3:11

[redacted]

SEP 17 2013

Re: PMN P-13-0248

Dear [redacted]:

This letter confirms, pursuant to 40 CFR 721.170(d)(2), the oral notification provided to you concerning the Agency's intent to issue a significant new use rule (SNUR) under Section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the chemical substance described in the premanufacture notice (PMN) referenced above. The PMN described the chemical substance as [redacted]. The pertinent regulations are found at 40 CFR Part 721.

EPA may issue a SNUR if it determines that (1) activities other than those described in the PMN may result in increased exposures to or releases of the PMN substance, and/or (2) concern exists about the substance's health or environmental effects. See 40 CFR 721.170(a). Under section 5(a)(1)(B) of TSCA, no person may manufacture (including import) or process a chemical substance for a use designated by EPA as a "significant new use" until 90 days after that person submits a significant new use notice (SNUN) to EPA. This allows EPA an opportunity to assess potential risk and identify any appropriate regulatory control actions. According to 40 CFR 721.5(a)(2), a person who intends to manufacture, import or process, and distribute in commerce, a chemical substance subject to a SNUR must submit a SNUN, unless they can document at least one of the following for each recipient of the substance from that person: (1) that person has given recipients of the chemical written notice of the existence of the SNUR (including its specific citation in 40 CFR part 721 subpart E), (2) the recipients have specific knowledge of the SNUR, or (3) the recipients cannot undertake any significant new uses designated in the SNUR.

In reviewing this PMN, the Agency identified human health concerns regarding the following effects: irritation, possible corrosion and acute toxicity (based on statements in the submitted MSDS); blood, thyroid, and neurotoxic effects (based on submitted test data with the PMN substance) and uncertain concern for immunotoxicity (based on data from lithium-based analogs). Consistent with 40 CFR 721.170(b)(3)(i) and (ii), the concern is based on test data on the PMN substance itself as well as test data for lithium salts. Based on this data, EPA expects potential toxicity to workers from inhalation and dermal exposures.

CONCURRENCES								
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Although EPA does not expect significant exposure to workers during the use identified in the PMN submission, if in the future the use changes from that described in your PMN, the potential for exposure could change correspondingly. Consequently, the Agency intends to promulgate a SNUR in which the restrictions stated in 40 CFR 721.80(o) and 40 CFR 721.63(a)(4) (Assigned Protection Factor (APF) of 10), will apply to this substance. The required respiratory protection will replace the dust mask currently listed in the MSDS. The SNUR will require submission of a SNUN to EPA at least 90 days before any consumer use. Corresponding recordkeeping at 40 CFR 721.125(a), (b), (c), (d), (e), and (i) will also be required. The SNUR will apply to your company, your customers for this substance, and any other manufacturer, importer, or processor of this substance. If you feel that these terms do not accurately reflect your intended activities for this chemical substance as presented in your PMN, please notify EPA as soon as possible.

EPA's decision to regulate this PMN substance with a SNUR was based partially on test data on the substance itself. Therefore, the SNUR preamble in the Federal Register will include suggested testing that would improve understanding of the potential human health effects posed by this substance. Companies with active product stewardship programs or companies who are considering whether to manufacture, import, process or use this substance for a significant new use are encouraged, but not required, to conduct the suggested testing on the substance. At this time, EPA has determined that the following test would help to characterize the human health effects of the PMN substance:

- Inhalation monitoring

EPA strongly encourages you, before performing any testing, to consult with the Agency pertaining to protocol selection. Many test guidelines are now available on the Internet at www.epa.gov/ocspp/pubs/frs/home/guidelin.htm. Although the guidelines provide general guidance for development of test protocols, they are not themselves acceptable protocols. Test data should also be developed according to TSCA Good Laboratory Practice Standards (GLPS) at 40 CFR Part 792 and through the use of methodologies generally accepted at the time the study is initiated. Failure to obtain protocol review by EPA or follow GLPS could result in data insufficient to permit a reasoned evaluation of the effects of the substance. Test reports should include protocols reviewed by EPA, certificate of analysis for the test substance, raw data, and results.

The review period for this PMN substance expired on July 30, 2013. After that date, you have become free to manufacture or import this substance in accordance with the SNUR provisions described above.

Please note that 40 CFR 720.102 requires you, within the first 30 days of commencement of manufacture or import of a PMN substance, to send a Notice of Commencement (NOC) to EPA. Because you submitted your PMN to EPA after the effective date of the electronic-PMN (eTSCA/ePMN) final rule (75 FR 773), you must use the eTSCA/ePMN software to submit your NOC. After April 6, 2012, all submissions are required to be submitted electronically via the internet using the Central Data Exchange (CDX). Please see

http://www.epa.gov/opptintr/newchems/epmn/epmn-index.htm for more information on the e-PMN software and directions on how to register and submit notices via CDX.

If you have any questions or comments, please contact Kenneth Moss, the SNUR Team Leader, at (202) 564-9232.

Sincerely,

Greg Schweer, Chief
New Chemicals Management Branch
Chemical Control Division (7405 M)